APR 1 2 2002

510(k) Summary of Safety and Effectiveness

K020995

This summary of safety and effectiveness is provided as part of the Premarket Notification for eFilm Workstation with Modules, in accordance with SMDA 1990.

Date Prepared:	March 15/2002
Submitted By:	eFilm Medical Inc. 500 University Ave, Suite 300, Toronto, Ontario Canada M5G 1V7
Contact Name:	Joseph A. Thomas
Contact Email:	joseph.thomas@efilm.ca
Contact Telephone:	(416) 204 9664 ext 291
Contact Fax:	(416) 204 9442
Device Trade Name:	eFilm Workstation with Modules
Device Common Name:	Picture Archiving Communications System (PACS)
Regulation Number:	892.2050
Device Classification:	Class II
Name:	Image Processing System
Predicate Device:	eFilm™ Workstation™
Predicate Device Manufacturer:	eFilm Medical Inc.
Predicate Device 510(k) Number:	K012211
Date Received:	07/16/2001
Decision Date:	07/31/2001
Decision:	Substantially Equivalent
Panel Code Device Reviewed by:	Radiology
Panel Code Device Classified by:	Radiology
Product Code:	LLZ
Regulation Number:	892.2050
Device Classification:	Class II

Device Description

eFilm Workstation with Modules is one of the components of a PACS (Picture Archiving and Communications System). eFilm Workstation with Modules is a software application that provides image viewing and manipulation in a diagnostic imaging setting. The functions of this application are applied to medical images that are acquired and stored on an image server in DICOM and/or other proprietary formats. eFilm Workstation with Modules can also transfer DICOM 3.0 images over a medical imaging network, as well as export images to applications in other proprietary formats.

Indications For Use

eFilm Workstation with Modules is a software application that is used for viewing medical images. eFilm Workstation with Modules receives digital images and data from various sources (including but not limited to CT, MR, US, RF units, computed and direct radiographic devices, secondary capture devices, scanners, imaging gateways or imaging sources). eFilm Workstation with Modules can be used to communicate, process and display medical images. Users have access to various image processing and measurement tools to assist them in viewing images. In addition, users can overlay templates on medical images to aid in preoperative planning. eFilm Workstation with Modules can be integrated with an institution's existing HIS or RIS for a fully integrated electronic patient record.

Typical users of eFilm Workstation with Modules are trained medical professionals, including but not limited to radiologists, technologists and clinicians.

Technological Characteristics

Both the eFilm Workstation with Modules and the eFilm™ Workstation™ are stand-alone software packages that can be used on more than one hardware platform. As long as minimum hardware requirements are met, the user is free to choose his/her own hardware platform.

Both systems allow digital image processing and measurement capability. Both systems can transmit to remote viewing stations over a medical imaging network.

eFilm Workstation with Modules does not contact the patient, nor does it control any life-sustaining devices. A physician providing ample opportunity for competent human intervention interprets images and information being displayed and/or printed.

Testing

eFilm Workstation with Module is tested according to the specifications that are documented in a Software Test Plan. Testing is an integral part of eFilm Medical Inc.'s software development process as described in the SOP-01: Product Development Process

Conclusion

The 510(k) premarket notification for eFilm Workstation with Modules contains adequate information and data to enable FDA-CDRH to determine substantial equivalence to the predicate device.

1. eFilm Workstation with Module has been and will continue to be manufactured according to the voluntary standards listed in the Voluntary Standards section (4.1) of this submission.

2. This submission contains the result of a hazard analysis and all potential hazards have been classified as minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2002

eFilm Medical, Inc.
% Mr. Neil E. Devine
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K020995
Trade/Device Name: eFilm Workstation with Modules
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 19, 2002
Received: March 28, 2002

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

510(k) Number: K020995

Device Name: eFilm Workstation with Modules

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEE DED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (per 21 CFR 801.109): ✓

OR

Over the Counter Use (optional Format 1-2-96): _____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
Radiological Devices
510(k) Number K020995